

REMARKS

The above-identified application has been carefully reviewed in light of the Examiner's office action mailed on February 26, 2009.

Submitted herewith is a Request for Extension of Time, and required fee, extending the period for responding to the Office Action to and including June 26, 2009.

Without conceding the correctness of any of the Examiner's rejections, the present claims have been amended to facilitate prosecution of the above-identified application and to obtain an early allowance. Applicant expressly reserves the right to seek patent protection for the original and previously pending claims and all other claims supported by the above-identified application in one or more later filed, related patent applications.

Specifically, claims 33, 44, 45, 55, 61, 68 and 70 have been amended to recite that the cooling device is to be placed or is placed on a skin region at a location on the upper back of a woman. Claim 70 has also been amended to delete "in anticipation of a hot flash associate with menopause. The added language is fully supported and enabled by the present specification, for example, at page 6, lines 10-15; page 8, lines 27-32; and the drawings and descriptions thereof.

In view of the deletion amendment to claim 70, applicant submits that claim 70 satisfies the requirements of 35 U.S.C. 112 first paragraph. Therefore, applicant respectfully requests that the rejection of claim 70 under this statutory provision be withdrawn.

Claims 33, 35, 36, 38, 41, 44, 45, 55, 57-59, 61-65, 68 and 70 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Patterson (U.S. Patent Publication 2003/0176904) in view of any of JP 2002119529 (JP '529) or U.S. Patent 6,224,899 (U.S. '899) and further in view of the article "Thermoregulating Physiology of Menopausal Hot Flashes: a review" (hereinafter Kronenberg et al). Applicant vigorously traverses this rejection as it pertains to the present claims.

The present invention is directed to methods of treating hot flashes associated with menopause in a woman.

Independent claim 33 recites a method which comprises providing a woman experiencing a hot flash associated with menopause with at least one cooling device in a package having instructions to remove the at least one cooling device from the package and to place the at least one cooling device on a skin region at a location on the upper back of the woman, which location is a site of origin of the hot flash, to thereby treat the hot flash associated with menopause.

Independent claim 55 recites a method which comprises removing a cooling device from a package having instructions for treating hot flashes associated with menopause using the cooling device on an upper back of a woman, and thereafter placing the cooling device on a skin region at a location on an upper back of a woman who is experiencing a hot flash associated with menopause, which location is a site of origin of the hot flash, the cooling device comprising a water-containing gel.

Independent claim 61 recites a method which comprises removing a cooling device from a package having instructions to place the cooling device at a location on an upper back of a

woman experiencing a hot flash associated with menopause, and placing the cooling device on a skin region at a location on an upper back of a woman who is experiencing a hot flash associated with menopause, which location is a site of origin of the hot flash.

Applicant has surprisingly and unexpectedly found that placing a cooling device on a skin region at a location on the upper back, for example, at a region in proximity to the cervical and thoracic vertebrae, such as between the C3 vertebrae and the T6 vertebrae, of a woman who is experiencing a hot flash, which is a site of origin of the hot flash, that the hot flash is effectively and advantageously treated.

The present claims make clear that the cooling device is placed on a skin region, that is on the surface, of the upper back of the woman. This skin region of the upper back of the woman is clearly and without doubt entirely different and distinct from the chest of the woman.

Further, and importantly the claimed methods allow a woman to easily and discreetly treat menopausal hot flashes at virtually any time, no matter where the woman is or what she is doing. For example, application of the cooling device to a skin region at a location on an upper back which is a site of origin of the hot flash is very effective in reducing the hot flash symptoms, and, in addition, because the upper back is a discreet location of the body, advantageously facilitates privacy in that the cooling device located on the upper back can be discreetly concealed under clothing.

Patterson, which was originally cited by the applicant in the above-identified application, discloses a self-adhering

cotton fabric cold strip, that is worn as a wrist band or an ankle band. Patterson discloses that the self-adhering cotton fabric cold strip has an envelope defining a sealed cold strip volume. Patterson discloses that a cooling gelatinous material is positioned on the cold strip volume and that a bandage sheet is fixed to the envelope. Patterson discloses that the bandage sheet defines a bandage adhesive for temporary adhesion of the cold strip to the skin surface of the user.

The Examiner cites paragraph 0012 of Patterson which discloses that every four hours she, that is the woman seeking relief from hot flash symptoms of menopause, places a strip around her waist or around her ankle or under her clothes across her chest. The Examiner cites Webster's II Dictionary to refer to the term "across" as meaning "from one side to the other". The Examiner then concludes that the disclosure of Patterson encompasses the application of the strip on the back of the user.

Patterson does not disclose, teach or suggest the present claims. For example, Patterson does not disclose, teach or even suggest providing a woman experiencing a hot flash associated with menopause with at least one cooling device in a package having instructions to remove the at least one cooling device from the package and to place the at least one cooling device on a skin region at a location on the upper back of the woman to thereby treat the hot flash associated with menopause where the location on the upper back of the woman is the site of origin of the hot flash, as recited in independent claim 33. Moreover, Patterson does not disclose, teach or even suggest a method of treating hot flashes associated with menopause in a woman which

includes placing a cooling device on a skin region at a location on the upper back of the woman who is experiencing a hot flash associated with menopause with the location on the upper back of the woman being a site of origin of the hot flash, as recited in independent claims 55 and 61.

The Examiner contends that Patterson's use of the phrase "across her chest" means on a skin region at a location on a upper back of a woman. Applicant vehemently disagrees.

In the context of the Patterson disclosure, it is clear that Patterson discloses placing the strip around the woman's wrist or around her ankle or under her clothes across her chest. See paragraph 0012 of Patterson.

This wording in Patterson, which the Examiner relies on heavily, makes abundantly clear that Patterson does not even consider, let alone contemplate placing the strip on a skin region at a location on an upper back of a woman, as recited in the present claims.

Patterson provides no suggestion whatsoever that the strip is to be placed at a location on a skin region of the upper back of the woman. Since the surface of a woman's chest is directly opposite from a skin region on the woman's upper back, to a large extent, Patterson teaches clearly, directly and away from the present invention. Any rational person, let alone one of ordinary skill in the art understands that, in the context of Patterson and the present claims, the terms "chest" and "a skin region on an upper back of a woman" are entirely different and distinct, one from the other.

In short, applicant submits that the teachings of Patterson are grossly deficient with regard to the present claims and, as noted above, actually teach away from the present claims.

The other documents cited by the Examiner do not supply the deficiencies apparent in the teachings of Patterson.

JP '529 does not disclose, teach or suggest the present invention. For example, JP '529 does not disclose, teach or even suggest any methods for treating hot flashes associated with menopause in a woman, let alone methods for treating hot flashes associated with menopause in a woman experiencing such a hot flash including providing a woman experiencing a hot flash with a cooling device in a package having instructions to place a cooling device on a skin region at a location on her upper back, which location is a site of origin of the hot flash, to thereby treat the hot flash (claim 33) or placing a cooling device on a skin region at a location on the upper back of the woman, which location is a site of origin of the hot flash, (claims 55 and 61), as recited in the present claims.

U.S. '899 does not disclose, teach or suggest the present invention. For example, U.S. '899, like JP '529, does not disclose, teach or even suggest any methods for treating hot flashes associated with menopause in a woman, let alone methods of treating hot flashes associated with menopause in a woman experiencing such a hot flash comprising providing a woman experiencing a hot flash with a cooling device in a package having instructions to place the cooling device on a skin region at a location on her upper back, which location is a site of origin of the hot flash, or placing a cooling device on a skin region at a location on the upper back of the woman, which

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location is a site of origin of the hot flash, as recited in the present claims.

Neither JP '529 nor U.S. '899 recognizes or even suggests the surprising, unexpected and unpredictable combination of advantages, that is effective and successful treatment of menopausal hot flashes in a discreet manner, while respecting the woman's privacy and allowing the woman to conduct her normal activities, achieved in accordance with the present claims. Both JP '529 and U.S. '899 are deficient with regard to the present claims, and do not supply the deficiencies apparent in Patterson.

The Examiner relies on Kronenberg et al as teaching that the onset of the hot flashes and sweating occur primarily on the chest and upper torso, e.g., trunk (citing page 1313, right column).

In fact, the provision referred to by the Examiner in Kronenberg et al is set forth as follows:

The onset of sweating is rapid and occurs primarily on the chest and upper torso.

Kronenberg et al discloses many other features of hot flashes which occur or may occur prior to the onset of sweating. For example, under the term "physiological changes", Kronenberg states that heart rate and skin blood flow peak within three minutes of hot flash onset. Thus, Kronenberg et al differentiates between hot flash onset and the onset of sweating.

Moreover, Kronenberg et al does not disclose, teach or suggest the present claims. For example, like JP '529 and U.S. '899, Kronenberg does not disclose, teach or even suggest any methods for treating hot flashes associated with menopause in a woman, let alone methods of treating hot flashes associated with menopause in a woman experiencing such a hot flash comprising providing a woman experiencing a hot flash with a cooling device in a package having instructions to place the cooling device on a skin region at a location on her upper back, which location is the site of origin of the hot flash, or placing a cooling device on a skin region at a location on the upper back of the woman which location is a site of origin of the hot flash, as recited in the present claims. Kronenberg et al does not mention or even suggest the back of the woman, let alone the upper back of a woman which is a site of origin of the hot flash, as in the present claims.

The Examiner states that in view of the cited prior art, it would have been obvious to provide a cooling sheet/strip applied across the chest to treat hot flashes comprising gelatinous material located between skin adhesive and cotton fabric layer.

As noted above, the cited prior art does not disclose, teach or even suggest the present claims which involve instructing a woman to place or placing a cooling device on a skin region at a location on an upper back of a woman who is experiencing a hot flash associated with menopause, which location on the upper back of the woman is being a site of origin of the hot flash and obtaining the benefits achieved by applicant and applicant alone.

The Examiner's basic position is that the term "across the chest" in Patterson encompasses a skin region on an upper back of a woman.

Applicant respectfully submits that this position is simply not reasonable. For example, as noted above, Patterson clearly states that the strip is placed around a woman's wrist or around her ankle or across her chest. It is clear, in the context of Patterson and the present claims, that Patterson contemplated only placing the strip on the woman's chest from the left side of her chest across the front of her body to the right side of her chest.

Applicant submits that this "across her chest" teaching of Patterson actually teaches away from the present invention in which a cooling device is placed on a skin region at a location on an upper back of a woman who is experiencing a hot flash which location on the upper back of the woman is a site of origin of the hot flash.

Patterson alone or in combination with one or more of the other references relied on by the Examiner simply does not disclose, teach or even suggest the present claims. None of the prior art combinations cited by the Examiner disclose, teach or even suggest the present claims and the surprising, unexpected and unpredictable combination of advantages achieved by applicant in accordance with the present claims.

The prior art provides no motivation or incentive, no other reasonable or rational basis and no common sense basis for one of ordinary skill in the art to combine, modify and extend the deficient teachings of the prior art to make obvious the present

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claims and obtain the surprising, unexpected and unpredictable combination of advantages of such claims achieved by applicant.

Only after knowing of applicant's disclosure and invention would one of ordinary skill in the art even attempt to practice the present claims. None of the prior art even suggests placing a cooling device on a skin region at a location on the upper back of a woman experiencing a hot flash which location is a site of origin of the hot flash, as in the present claims. The "across the chest" disclosure of the primary reference Patterson, when Patterson is properly considered as a whole, makes clear that Patterson teaches away from, and is in direct contrast to, the present claims.

In view of the above, applicant submits that the present claims, that is claims 33, 35, 36, 38, 41, 44, 45, 55, 57-59, 61-65, 68 and 70, are unobvious from and patentable over Patterson in view of JP '529 and/or U.S. '899 and further in view of Kronenberg et al under 35 U.S.C. 103(a).

Applicant submits that each of the present dependent claims is separately patentable over the prior art. For example, the prior art does not disclose, teach or suggest the present apparatus and systems including the addition feature or features recited in any of the present dependent claims. Therefore, applicant submits that each of the present claims is separately patentable over the prior art.

In conclusion, applicant has shown that the present claims, that is, claims 33, 35, 36, 38, 41, 44, 45, 55, 57-59, 61-65, 68 and 70 are unobvious from and patentable over the prior art under 35 U.S.C. 103 (a). Therefore, applicant respectfully

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requests the Examiner to pass the above-identified application to issuance at an early date.

Applicant respectfully requests that the Examiner, before taking any action on this paper which is adverse to applicant, telephone applicant's attorney to set up an interview regarding the above-identified application.

Respectfully submitted,



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